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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,501	02/09/2004	Leena Peltonen	021825-006300US	2308

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,501	PELTONEN ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41,43,44,48,51,52,56 and 75-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41,43,44,48,51,52,56,75 and 77-86* is/are rejected.

7)☒ Claim(s) *41,43,44,48,51,52,56 and 75-86* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. It is again noted that this application has been transferred from Ex. D. Cho to Ex. D. Johannsen. Upon further consideration, the claims have been rejected on new grounds, as set forth below. **Accordingly, this action is NON-FINAL**.

Election/Restrictions

2. Upon consideration of Applicant's remarks and traversal of December 18, 2007, the further restriction requirement of October 18, 2007 is withdrawn. All of the claims corresponding to original Group I have been examined. However, it is noted that in accordance with the original restriction requirement of October 11, 2006, SEQ ID NO: 3 remains withdrawn.

Claim Objections

3. Claims 56, 75, and 77-82 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 76, from which all of the instant claims depend, requires a nucleic acid molecule "comprising SEQ ID NO:3 or SEQ ID NO:5". However, claim 77 (from which each of claims 56, 75, and 78-82 depend) encompasses any molecule "consisting of a sequence of at least 14 consecutive nucleotides of SEQ ID NO:3, SEQ ID NO:5, or a complementary sequence thereof." Thus, claims 56, 75, and 77-82 do not require all the limitations of the claim from which they depend (claim 76), and are not proper dependent claims.

4. Claims 83-85 are also objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims do not require all the limitations of the claim from which they depend, claim 41 (which claim requires a molecule comprising one of SEQ ID NOs 1, 3, or 5 or one of the complements thereof).

5. Claims 41, 43-44, 48, 51-52, 56, 75-86 are objected to because of the following informalities: the claims encompass non-elected subject matter (specifically, SEQ ID NO: 3). Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 41, 43-44, 48, 51-52, 56, 77-79, and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Birren et al (GenBank Accession No. AC016516, April, 2000), and with further regard to claims 51-52, as evidenced by Osoegawa et al (Genome Research 11(3):483-496 [March 2001]).

Birren et al disclose the *Homo sapiens* chromosome 2 clone RP11-329I10, which comprises instant SEQ ID NO: 1 (at nucleotides 81,932-82,111; see provided alignment), and which includes a sequence identical to instant SEQ ID NO: 5 with the

exception of 3 mismatches (see provided alignment). A review of the features of the Birren et al clone indicates that the sequence noted above is genomic DNA found on a single BAC clone; therefore, Birren et al teach a nucleic acid molecule meeting the requirements of claim 41 and 43. It is an inherent property of the genomic DNA of Birren et al that it includes "part of a gene," as genes are composed of nucleotides. Accordingly, the molecule of Birren et al meets the requirements of claim 44. Further, the BAC taught by Birren et al is a type of vector, as required by claim 48. Regarding claims 51-52, Birren et al teach that RP11-329I10 was obtained from clone library RPCI-11, and the Osoegawa et al reference disclose that this library was constructed in E. coli host cells (see entire reference, particularly page 494). Thus, Birren et al inherently disclose a product meeting the requirements of claims 51-52. Regarding claim 83, the sequence taught by Birren et al includes position 324 and hundreds of nucleotides of flanking sequence on either side thereof (see sequence alignment).

With regard to claims 77-79 and 56, it is again noted that the claims do not properly depend from, and do not include all the limitations of, claim 76 (from which they depend).

Regarding claim 77, the claims encompass any molecule complementary to a sequence consisting of at least 14 consecutive nucleotides of SEQ ID NO: 5; thus, the BAC clone taught by Birren et al anticipates the claim. With further regard to claim 78, as Birren et al discloses a vector including a complete complementary strand, the clone of Birren et al also meets the requirements of claim 78. Regarding claim 79, as the

claim is further limiting of the "sequence" of claim 77 (not of the molecule of claim 77), the complementary strand of Birren et al also meets the requirements of claim 79.

Regarding claim 56, the body of the claim defines the complete structure of the claimed product ("comprising the nucleic acid molecule of claim 77"), and the clone disclosed by Birren et al meets the structural requirements of the claim. The preamble statement of the intended use of "for diagnosing or assessing an individual's predisposition to develop adult-type hypolactasia" is therefore not accorded any patentable weight (see MPEP 2111.02).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 75 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren et al (GenBank Accession No. AC016516, April, 2000) in view of Ahern.

With regard to claim 75, it is again noted that the claim does not properly depend from, and does not include all the limitations of, claim 76 (from which it depend).

Birren et al disclose the *Homo sapiens* chromosome 2 clone RP11-329I10, which comprises instant SEQ ID NO: 1 (at nucleotides 81,932-82,111; see provided alignment), and which includes a sequence identical to instant SEQ ID NO: 5 with the exception of 3 mismatches (see provided alignment). A review of the features of the Birren et al clone indicates that the sequence noted above is genomic DNA found on a single BAC clone; therefore, Birren et al teach a nucleic acid molecule meeting the requirements of claim 41 (from which the instant claims depend). With further regard to claim 75 (which depends from claim 77), the claim encompasses any molecule complementary to a sequence consisting of at least 14 consecutive nucleotides of SEQ ID NO: 5; thus, Birren et al teach a BAC clone meeting the requirements of the claim.

Birren et al do not teach packaging their molecules into kits, as required by the claims.

Ahern teaches that premade reagents provided in kit form are convenient and save researchers time and money (see p. 3/5-4/5). In view of the teachings of Ahern, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Birren et al so as to have packaged the molecules taught by Birren et al into a kit. An ordinary artisan would have been motivated to have made such a modification in order to have provided the

molecules of Birren et al to practitioners in a convenient format for the advantages of efficiency and cost-effectiveness.

11. Claims 79-82 and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren et al in view of O'Neill et al (US 6,124,092 [26 Sept 2000]).

With regard to claims 79-82, it is again noted that the claims do not properly depend from, and do not include all the limitations of, claim 76 (from which they depend). It is also noted that this rejection applies to claim 79 to the extent that it is drawn to molecules consisting of between 14-24 nucleotides.

The teachings of Birren et al are set forth in the preceding paragraph. Birren et al do not teach molecules of the length set forth in claim 79, or labeled as in claims 80—82. Further, Birren et al do not teach a primer or primer pair as in claims 84-85. However, Birren et al do teach that their sequence is a "working draft" sequence (see Comment section in provided alignment with Accession No. AC016516). Thus, the teaching of Birren et al suggest the need to do additional, confirmatory sequencing of their clone.

O'Neill et al disclose rapid methods for generating and sequencing amplification products (see entire reference, particularly, e.g., col 2, line 64-col 4, line 53). O'Neill et al disclose the use of primers capable of specifically hybridizing to target sequences that are "typically 18-36 nucleotides in length" (see, e.g., col 6, lines 24-56), and the use of primers that are fluorescently labeled or radiolabeled in their methods (see, e.g., col 11, line 48-col 12, line 17).

In view of the teachings of Birren et al and O'Neill et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have prepared any primers having the lengths and/or labels taught by O'Neill et al that could be used in the specific amplification of the product of Birren et al, and thereby to have produced numerous different primers and primer pairs meeting the requirements of the instant claims. An ordinary artisan would have been motivated to have prepared such molecules for use in confirming the sequence of the clone taught by Birren et al, as suggested by Birren et al's statement that their sequence is a "working draft." An ordinary artisan would have been motivated to have employed the primer design guidance of O'Neill et al in order to have prepared primers usable in the method of O'Neill et al, for the advantage of rapidly performing the confirmatory sequencing suggested by Birren et al.

Conclusion

12. The art made of record and not relied upon is considered pertinent to applicant's disclosure. Venter et al (US 6,812,339 [14 October 2004; filed 10 September 2001]) disclose the same variant claimed herein by applicants (see, e.g., SEQ ID NO: 88136 of Venter et al). However, Venter et al does not constitute prior art with respect to the instant application, as the variant was first disclosed in original application 09/949,016, filed September 10, 2001. It is also noted that the prior art does not teach or suggest an isolated nucleic acid comprising instant SEQ ID NO: 5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634